



**CIRCULATORY SYSTEM DEVICES PANEL
AGENDA*****September 12, 2013***
Circulatory System Devices Panel
515i Classification Panel
Gaithersburg Hilton

On September 12, 2013, the committee will discuss and make recommendations regarding the proposed classification of Membrane lung for long-term pulmonary support systems (ECMO), one of the remaining preamendments Class III devices regulated under the 510(k) pathway. A membrane lung for long-term pulmonary support refers to the oxygenator component of an extracorporeal circuit used during long-term procedures, commonly referred to as an ECMO. An ECMO procedure provides assisted extracorporeal circulation and physiologic gas exchange of a patient's blood when an acute (reversible) condition prevents the patient's own body from providing the physiologic gas exchange needed to sustain life. ECMO is intended for patients with acute reversible respiratory or cardiac failure, unresponsive to optimal ventilation and/or pharmacologic management.

8:00 a.m.	Call to Order Introduction of Committee	Richard Page, M.D. Chairperson
	Conflict of Interest Statement	Jamie Waterhouse, M.B.A. Designated Federal Officer
8:15 a.m.	Reclassification Presentation	Marjorie Shulman, M.B.A. Director, Premarket Notification (510(k)) Program
8:30 a.m.	Questions from Committee	
8:45 a.m.	FDA Presentation	
10:30 a.m.	Question from Committee	
10:45 a.m.	Break	
11:00 a.m.	Panel Deliberations	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Questions from Committee	
2:15 p.m.	Panel Deliberations	
3:00 p.m.	Break	
3:15 p.m.	FDA Questions to the Panel	
6:00 p.m.	Adjournment	

*** Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.